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510(k) Summary

Agfa Registration and Fusion

Common/Classification Name: Picture Archiving and Communications System (PACS), 21 CFR 892.2050
Proprietary Name: Registration and Fusion

Agfa HealthCare Corporation
10 South Academy Street
Greenville, SC 29602-9048

JAN 17 2008

Contact: Tom Holbrook, Prepared: November 9, 2007
Telephone: (519) 746-6210 ext. 3297
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A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's Registration and Fusion software. The predicate device, Mirage 5.5 (K043441), manufactured by Segami Corporation.

The new device is similar in indications and intended use as the predicate device.

B. DEVICE DESCRIPTION

Medical Data Registration and Fusion R 1.0 is a PACS plug-in (accessory). It is an image analysis software package that establishes the geometrical relationship between different DICOM 3.0 compliant 3-D medical data sets from PET, MR and CT imaging (registration[6]).

The matched images are displayed (fusion[7]) by either the use of semi-transparent overlays or by displaying them side-by-side.

Registration and fusion facilitates the comparison of PET/CT, PET/MRI, CT/CT, MRI/MRI, CT/MRI image data sets for use in:

- The general radiology department for various lesions.
- The oncology department for various cancerous lesions.

Definitions:
[6] Image Registration: The alignment of one or more [medical] images to a reference image in order to facilitate geometric comparison. This is a numerical operation that results in the computation of an explicit mathematical transformation between every point in the registered image sets.
[7] Image Fusion: Registration forms the basis of image fusion in the sense that the geometrical alignment of images is a prerequisite. The notion of "fusion" takes this a step further by considering how to visualize the content of different images representing the same object [organ, anatomical region, etc.]. Such techniques include the use of overlays, semi-transparent renderings, etc.

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- The neurology department for various lesions.

The rigid registration used in the application, aims to help the clinician navigate to the same anatomical location in both image sets.

The Medical Data Registration and Fusion software runs on Agfa's PACS workstations (Impax 5.3 and 6.3 workstations).

Typical users of this system are trained professionals, including but not limited to radiologists, referring physicians, radiation therapists, and physicists. Registration may also be used by radiographers for use of the images by radiologists. Registration and fusion has application in general radiology, oncology and neurology.

C. INTENDED USE

Registration and Fusion (Basic and Extended) are intended for the simultaneous visualization of multiple medical images of the same patient. The application can assist the user in visually matching and comparing anatomical studies taken at different times or acquired via different imaging modalities (Basic: CT-CT, CT-MR, MR-MR, Extended: CT-PET, MR-PET) as well as assist in making measurements. It is primarily used in the fields of diagnostic radiology, neurology and oncology.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's Registration and Fusion Software has similar indications and intended use as the legally marketed predicate devices.

The differences do not modify the intended diagnostic or therapeutic effect. It is intended for registering and fusing volumetric medical image data sets for the purpose of diagnosis and treatment follow-up.

Registration and Fusion is used primarily in the fields of general radiology department for various lesions, oncology for various cancerous lesions and neurology for various lesions.

Descriptive characteristics and data provided in this submission are sufficiently precise to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are the same in the proposed and predicate device. All devices use similar, commercially available, computers with Windows® operating systems. All operate on DICOM images. All provide rigid registration of CT, MR and PET image data sets

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and SUV / Image intensity quantification.

F. TESTING

Registration and Fusion has been tested for compatibility with Agfa's Impax® PACS Systems.

G. CONCLUSIONS

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2008

Agfa HealthCare Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K080013
Trade/Device Name: Registration and Fusion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 2, 2007
Received: January 3, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080013

Device Name: **Registration and Fusion**
Indications for Use:

Registration and Fusion (Basic and Extended) is indicated for the simultaneous visualization of multiple medical images of the same patient. The application can assist the user in visually matching and comparing anatomical studies taken at different times or acquired via different imaging modalities (Basic: CT-CT, CT-MR, MR-MR, Extended: CT-PET, MR-PET) as well as assist in making measurements. It is primarily used in the fields of diagnostic radiology, neurology and oncology.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080013